UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/823,368	04/12/2004	Steven A. Bogen	1159.1004-006	4846

21005 7590 09/10/2009

HAMILTON, BROOK, SMITH & REYNOLDS, P.C.
530 VIRGINIA ROAD
P.O. BOX 9133
CONCORD, MA 01742-9133

EXAMINER	
ALEXANDER, LYLE	

ART UNIT	PAPER NUMBER
1797	

MAIL DATE	DELIVERY MODE
09/10/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

RECORD OF ORAL HEARING

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte STEVEN A. BOGEN and HERBERT H. LOEFFLER

Appeal 2009-005697
Application 10/823,368

Oral Hearing Held: Tuesday, July 21, 2009

Before EDWARD C. KIMLIN, CHARLES F. WARREN and
TERRY J. OWENS, Administrative Patent Judges

ON BEHALF OF THE APPELLANTS:

MARIA L. CEDRONI, ESQUIRE
Hamilton, Brook, Smith & Reynolds, P.C.
P.O. Box 9133
530 Virginia Road
Concord, Massachusetts 01742-9133

The above-entitled matter came on for hearing on Tuesday, July 21, 2009, commencing at 2:02 p.m., at the U.S. Patent and Trademark Office, 600 Dulany Street, 9th Floor, Hearing Room A, Alexandria, Virginia, before Jennifer A. Hipp, Notary Public.

MR. KIMLIN: Good afternoon, Ms. Cedroni.

MS. CEDRONI: Good afternoon.

MR. KIMLIN: You can begin when you're ready.

MS. CEDRONI: Good afternoon. My name is Maria Cedroni and I am with the law firm Hamilton, Brooks, Smith, Reynolds and I represent the Appellant in this Appeal. I just want to talk a little bit about the overall invention that we're claiming, describe the rejection including the three references that the Examiner is maintaining in his Answer and discus why the invention is not obvious in view of these references.

Just for the sake of providing context I want to describe the invention by starting off with the field of the invention and in this case the field of the invention - the invention first of all is a dispensing assembly for dispensing liquid reagents onto microscope slides. In reality what this is, is it's used for automated microscope slide staining.

Now as part of the record we submitted a declaration of Dr. Ron Zeheb. In this declaration, what Dr. Zeheb is doing is he's laying out the state of the art at the time of the invention as of 1994. So in his declaration he details what kinds of microscope slide staining happened in 1994. These are essentially two different types. First, there's the routine slide staining and second is advanced microscope slide staining.

Routine slide staining is pretty much what it sounds like. It's rather routine, the protocols were well set, and typically done in batches where all the samples were treated the same way. Advanced staining including three different kinds of staining and I'll get into those in more detail when I talk a little bit more about the invention. So the three different kinds of advance staining were special stains. These were ones that required greater attention. The protocols weren't as set and you had to - it's actually considered an art by the technicians.

They had to watch the samples mostly to see when a certain color was achieved they could know when to continue with the protocol.

MR. KIMLIN: But the claims really aren't directed to do these types of stains or any particular stain?

MS. CEDRONI: No, they are not. I'm trying to put into context the field because it's important to figure out why the invention wasn't obvious. The field of the invention really was microscope slide staining so --

MR. KIMLIN: My point is, though, that your claims are extending beyond this field.

MS. CEDRONI: Well, this is not - what I'm trying to do is not describe the scope of the claims but to put into context why the invention is not obvious. So moving on to the invention itself, it improved on the prior art devices by employing a more efficient method of heating and combine that with an automated liquid dispenser and a microprocessor and the ability to move either the liquid dispenser, the platform on which the slides rest or both.

Now before I get into the specifics of the claims I would just like to talk about a few specific embodiments of the invention. Unless you're using a different version, I'm using the published application so.

MR. WARREN: We just have the basic specifications.

MS. CEDRONI: Okay. I have that too then. So turning to figure 5 of the specification then, this is a complete embodiment of the invention and underneath the slide cover which is item number 532 on there, and that's where the microscope slides are. In this embodiment the slides rotate to the dispensing station which is on the left hand side of the diagram and is item 508, where the liquid reagent is dispensed onto the slides. The dispensing station in this embodiment is stationary.

What happens is the liquid dispensers which are the items labeled "CP" for cartridge pumps rotate because the reagent rotor which is item 506 to the dispensing station. Now if you turn to figure 1 you can see how the liquid dispenser actually works. The cartridge pump which is again item CP pulls the volume of liquid reagent.

When the cartridge pump is at the dispensing station which is that large item on the previous figure and the slide is in position under the dispensing station, the hammer which is item 10 pushes on the metering chamber and liquid reagent is dispensed through the nozzle, item 5 onto the slide. So in this particular embodiment what you have is the liquid reagent - the liquid dispenser that moves and you have the slides that move.

Now figures 6 and 7 describe the heating system of the invention. So figure 6, item 514 is the slide frame base which is the platform which is what supports the slides in the plural heated surface areas.

So the platform includes plural heated surface areas which is figure 7 is item 516 so these are the areas the microscope slides directly rest on.

So in particular what the claims are directed to is the dispensing assembly having a platform which as I've described, have plural heated surface areas. Those plural heated surface areas are heated by an electric heater which is underneath the plural heated surface areas. The plural heated surface areas really are areas where the microscope slides sit. They sit directly upon the heated surface area that is in contact with and directly underlies the microscope slide.

Now of course there are other parts of the claim as well but this is mostly what we're relying on. The claims also call for plural temperature sensors on the platform for sensing the temperature with respect to the heated surface areas. The benefits of the invention, by having plural heated surfaces it allows greater control of the reaction conditions because you can program the microprocessor which is also part of the claims, to selectively heat slides and it's also a more efficient way of heating microscope slides because it requires less energy to heat just the area underneath the slide and also is unlike incubators which were in the prior art.

It doesn't require heating all the various components that are also within the incubating chamber. This combined with the fact that the liquid dispenser and the platform are adapted for relative movement. And the microprocessor, which is another part of the claims, also allows for greater control of reaction conditions than the prior art.

Now moving onto the rejection, the Eexaminer has rejected all of the pending claims as obvious over two primary references, Heidt or Kerr,

each in view of Potter. Another thing these references alone or in combination do not render the claimed invention obvious for at least three different reasons. First, if you combine all the references you still don't arrive at the claimed invention. Second, Heidt and Kerr which are the two primary references actually teach away from the claimed invention.

And finally, there is no motivation in the art as described by Dr. Zeheb to combine or alter the teachings of the three references to come up with the invention that's claimed. Now first turning to the two primary references, these are similar devices in Heidt and Kerr. Heidt and Kerr teach a chemical analyzer that accommodates reagent test slides.

In fact, in Heidt itself Heidt distinguishes the apparatus that he claims from the type of apparatus that we are claiming. If you look in column 1 of Heidt he talks about his embodiment and describes it as a chemical analyzer and then directly contrasts that with wet chemistry analyzers which - and I'm quoting here - "such as described above are usually complex and expensive, required skilled operators, and necessitate a considerable expenditure of time and effort and repetitive cleaning operations." So there he's saying "my invention is not a wet chemistry analyzer."

It is not the dispensing assembly that we're claiming in this application. Kerr also utilizes this same type of device that uses chemical analyte slides. Chemical analyte slides are slides that have dry reagent on them. The reagent is impregnated onto the test slide itself and if you drop a sample onto that slide and depending on the reaction between the sample

you dropped onto it and the reagent that's impregnated on this test slide, you have your outcome of the test results.

So for example, both Heidt and Kerr talk about a dispensing assembly - or I'm sorry, a chemical analyzer where a drop of blood is dropped onto these chemical analyte slides and depending on the color reaction you can determine whether or not the subject has a particular disease or not.

MR. WARREN: Counselor?

MS. CEDRONI: Yes.

MR. WARREN: You claim calls for the dispensing area for the slide, correct?

MS. CEDRONI: Yes.

MR. WARREN: Currently in clause C assumes that there will be a biological sample on that slide?

MS. CEDRONI: Yes.

MR. WARREN: So we can assume with the prior art that you can put a slide on there that has biological sample on it and the prior art will dispense some liquid onto that slide, correct, such as a drop of blood?

MS. CEDRONI: Our claims have a microscope slide that has a biological sample on the slide itself.

MR. WARREN: It says "adapted to have."

MS. CEDRONI: Okay, yes.

MR. WARREN: So I'm saying that if somebody in the prior art took all those - took an apparatus and put a slide on there which already had

a biological substance on it, perhaps antibodies, perhaps antigens, and put a drop of blood on them would that be your apparatus?

MS. CEDRONI: I think that is correct. That could be. What our claims call for is a microscope slide adapted to have a biological sample and just dropping a reagent onto it so that reagent could in fact be a biological sample.

MR. WARREN: Well, what I'm saying is if you drop a drop of blood onto it I'm not sure you can say that that wasn't something that was going on in the slide, for example, if you want to check out that drop of blood against an antibody or if you want to check the antibodies in that blood against an antigen.

MS. CEDRONI: Right, and I think that is something that could be encompassed by the claims of our patent. What I'm --

MR. WARREN: Well, also they're encompassed by the prior art.

MS. CEDRONI: Well, not by Heidt and Kerr, the two references I'm talking about here. Here they aren't using microscope slides. What they're using are chemical analyte slides which are very different from a microscope slide which is typically a flat piece of glass that you will use to put underneath a microscope and look at whatever is on the microscope slide.

MR. WARREN: Why couldn't you apply a microscope on the slides are the prior art?

MS. CEDRONI: For Heidt and Kerr the slides are impregnated with a reagent so when the sample is dropped onto the microscope slide

there's a color reaction between the sample and the reagent on the slide and so what you do is, it's just measured colorimetrically.

MR. WARREN: But you can't take that and put it under the microscope?

MS. CEDRONI: You could but it wouldn't help you determine the outcome of the reaction.

MR. WARREN: But how does that affect your dispensing assembly?

MS. CEDRONI: The slides, the chemical analyte slides of Heidt and Kerr are not in fact microscope slides. They are reagent slide.

MR. WARREN: But they could still be viewed under a microscope, could they not?

MS. CEDRONI: I'm not sure of the dimensions of them, in all honesty but they're very different things.

MR. WARREN: So the microscopes vary with the very large, the very small to accommodate any shape that you would like to put under there.

MS. CEDRONI: Using that analysis there are many different things that you could put under a microscope that wouldn't be a microscope slide.

MR. WARREN: Well, if it's something that you can slide under a microscope aperture then it would be a microscope slide, would it not?

MS. CEDRONI: I don't think that's entirely true especially for one of skill in the art that would be looking at these devices and recognizing

Heidt and Kerr as chemical analyzers, especially given how Heidt describes his invention.

MR. WARREN: One of ordinary skill in the art is one who routinely works in the lab or anyone who is only a technician. Would they not adapt to the materials at hand in order to carry out their experiments including an apparatus which they may happen to have?

MS. CEDRONI: I think when someone is using a device such as the ones described in Heidt and Kerr they're using them for something other than microscope slide staining as that is commonly recognized. What you're doing is you have the slides with the reagent and you're dispensing just one sample, you're dispensing blood onto the microscope - I'm sorry, onto the chemical analyte slide.

For this embodiment if you look at our invention it calls for dispensing of reagent. It's not calling for a sample.

MR. WARREN: Well, are you aware that there are decisions that say the material on which an apparatus works is not a part of that apparatus?

MS. CEDRONI: Yes, I know that those cases exist but in terms of what the invention is, it is a liquid dispenser. It is a dispensing assembly for dispensing liquid reagent onto a microscope slide so the field of the invention, again, is microscope slide staining.

MR. KIMLIN: Why wouldn't blood be considered a reagent?

MS. CEDRONI: It certainly could be but in terms of Heidt and Kerr all you dispense is that. For microscope slide staining typically what you do is you dispense a reagent onto the sample that you have sitting on the

slide. You then have to wash that reagent off and then typically you have more than one reagent. You have another reagent and you do another wash.

It's very different and I think we're getting farther away from the invention than I really want to right now. The point is that Heidt and Kerr really are directed to these chemical analyzers and the needs associated with those chemical analyzers are very different from the needs associated with the liquid dispensing assembly that is claimed.

Furthermore, both Heidt and Kerr teach incubators to heat slides and what an incubator is, is it's an area that's heated. The air is heated in that area and the slides are heated through the air basically. There's no direct heat to the slides. And for these chemical analyte slides you had a set temperature that you wanted to get the slides heated up to, to facilitate the reaction.

These conditions really needed to be the same for each slide if the reaction were to mean anything.

MR. WARREN: But how does clause A distinguish over that particular feature in the prior art?

MS. CEDRONI: So in both Heidt and Kerr there's - it's an incubator. There's a heat source but what it's doing is heating the entire area so the entire area that the slides happen to be in reach a certain temperature. In clause A --

MR. WARREN: The microscope slides won't radiate heat supplied by the electric heater they're under?

MS. CEDRONI: No, I don't believe they do. In Heidt it discloses a heating system where the air inside a cabinet enclosure is heated

and the slides are heated indirectly by radiation heat basically. So what you have in clause A is you have a platform that has more than one heated surface area.

That surface area is heated by an electric heater that is underneath the heated surface area and each surface area is adapted to be in contact with and underlie a microscope slide so there's direct contact between the heated surface area and the slide which allows for selective heating of the slides. And as I stated previously, it allows for more efficient heating of the slides because all you have to do is heat that one area.

Also in both Heidt and Kerr if you look closely at how the things are actually heated, in both of them the slides are inserted into the platform or into some other area to hold the slides so what you have is the slides are inserted in there. There's nothing underneath the slides so there's nothing underlying the slides as there are in our claims.

Turning now to Potter, Potter is the secondary reference the Examiner has used in combination with Heidt or Kerr for his rejection that the stated claims are obvious. Potter discloses an apparatus capable of independently regulating the heating of each sample in a sample container designed for rapid heat transfer to a set temperature.

So really what Potter is designed for is a sample container as in a well. You put liquid samples into the wells and then you need to vary the heat rapidly. This is usually used for things like DNA amplification so for instance, or polymerase chain reaction, PCR, you need to heat the sample different ways. You have to have really high temperature and then very quickly you have to come down to another temperature and then change the

temperature so really it's talking about rapid heat transfer, rapid temperature changes for Potter.

Now Potter is designed, like I said, for rapid heat transfer and usually you have a small amount of sample or expensive reagents and because you are changing temperature so much one of the primary concerns is to reduce evaporation. And the way that you do this is with the lid so what this means is that the system of Potter is completely closed off to the outside environment as you need to prevent evaporation.

And this is telling in Potter. Potter does not have a liquid dispenser. There's no automation and nothing moves in Potter. This is completely incompatible with the dispensing assembly as claimed. If you have something where the samples are sealed with a lid you can't dispense reagent into it. One of skill in the art looking to Potter is not going to see something that would be useful for microscope slide staining, especially in this embodiment where you have a reagent that is dropped down onto the microscope slide and where you have a lot of moving parts.

So there are a lot of differences between Heidt and Kerr and Potter and the claimed invention. First, none of them are actually directed to microscope slides. None of them are directed to the field of the invention wherein such that one of skill in the art would consider combining the three together to come up with the invention claimed.

Moreover, they don't teach the plural heated surface areas. The primary ones don't teach plural heated surface areas and Potter doesn't teach plural heated surface areas in a way that's actually adapted to microscope slides.

MR. KIMLIN: Doesn't plural heated surface areas include and encompass a uniform surface area heated which in turn has plural heated surface areas?

MS. CEDRONI: I'm sorry, can you say that again?

MR. KIMLIN: In other words, if you had a uniform heated plate wouldn't that have plural heated surface areas that are heated?

MS. CEDRONI: It doesn't have plural heated surface areas where each is heated by an electric heater which is what's claimed.

MR. KIMLIN: That's another step.

MS. CEDRONI: Does that answer your question, I'm sorry?

MR. KIMLIN: Well, you added on a limitation that you cited previously.

MS. CEDRONI: I'm sorry. The claims call for a plural heated surface area where the heated surface areas are heated by an electric heater that they're under so underneath it there is an electric heater and Heidt and Kerr don't teach this and Potter does not teach this in a way that is useful for a microscope slide.

So all told we have two primary references that fail to teach the heating as claimed and are not directed to microscope slide staining. The secondary reference, Potter is also not directed to microscope slide staining, doesn't teach a heating system that's useful for microscope slide staining and doesn't have a liquid dispenser or any moving parts.

This all comes down to, why would somebody of skill in the art try to combine these three references to achieve the invention as claimed. And we argue that there is no motivation and this is where the declaration of

Dr. Zeheb comes in. What he has explained is what the state of the art was. You have routine staining and advanced staining that I talked about.

Within the prior art, in the prior art of the time one of skill in the art would not have seen the need to have the heating system combined with the liquid dispenser and the relative movement of the claimed invention. This is because it would have been costly and complex to add, to modify the three references to come up with the claimed invention.

First you need to modify the devices taught in Heidt and Kerr to include plural heated surface areas, each heated by an electric heater. That's not simple or trivial. Second, you would need to further modify the devices to include plural temperature sensors and third, you would need to connect all of these to a microprocessor. Finally, this would be complicated by the fact that you have relative movement between the liquid dispenser and the microscope slides.

That means either the liquid dispenser, the microscope slides, or both move.

MR. KIMLIN: Let me interject that the claim language, the platform having plural heated surface areas each heated by an electric heater thereunder does not require separate electric heaters. The claim simply requires separate sensors for plurality.

MS. CEDRONI: So the claim reads "the platform having plural heated surface areas, each heated so that each heated surface area heated by an electric heater thereunder.

MR. OWENS: What if it were a big electric heater that heated the whole thing?

MR. KIMLIN: A uniform heat plate.

MS. CEDRONI: I read the claims as having the surface areas are each heated by an electric heater thereunder. Even if you read it as you are saying where you have one electric heater on the platform, none of the references, Heidt and Kerr still don't teach that, especially where you have the heated surface area further being adapted to be in contact with and underlie a microscope slide.

That's not taught by Heidt or Kerr. So in Heidt and Kerr, as I stated previously those are incubators. You have a heated surface. You don't have the heated surface area. There really is no heated surface area. What's happening is you have an incubation chamber where everything in that incubation chamber is heated.

Further, as I stated the chemical analyte slides of Heidt and Kerr are inserted into open space so if you imagine that you have a platform that has little carve-outs in it, the slide slides into that but there's nothing underneath that slide. So you definitely would not have heated surface area if it's in contact with and underlying the slide.

So again, there'd be no motivation to alter Heidt and Kerr or Potter to come up with the claimed invention. Routine staining, as I discussed was typically done in batches where all the samples were treated exactly the same. You put a bunch of slides into a basket and you dipped them into reagent and that's all you did. And they didn't require heating.

The advances staining, there were three different types. The one that I'll talk about is special stains and this is the one that - this invention actually did enable and in the prior art they didn't believe that this could

actually be automated because it was such an art. You had to watch the sample to figure out when it achieved a certain color to know when to continue with protocol.

Dr. Zeheb has included in his declaration, exhibits that describe protocols for special staining that show that you had - that it really didn't seem very suited to automation because you had to watch the reaction so closely which just isn't something you can automate or they didn't think you could automate.

And again, as you have mentioned the claims are not specifically directed to special stains. What we're trying to show you is one of skill in the art of the time had no motivation. Routine stains didn't require heating so there's no reason to have the heaters there. The two other types of advanced staining are immune histochemistry which is used to assess an antigen/antibody response and those all required heating to the same temperature, about body temperature usually.

And this is where the incubators came in so those were useful because everything had to be heated to the same common temperature so you didn't need the heating that this system has. And for in situ hybridization which is the last advanced stain, really what you're using, an example of this is you'd have a DNA probe that's labeled radioactively to determine if a particular DNA sequence exists in a given tissue sample.

In these systems you have to heat the samples up very high and again, evaporation is an issue so for those you had a cover slip or you had something covering the sample so you couldn't actually dispense reagent on it so this is the final advanced stain and there is just no motivation, there was

no need for the dispensing assembly. No perceived need, I should say, for the invention that is claimed.

MR. KIMLIN: Your time is about up, Ms. Cedroni.

MS. CEDRONI: So for these reasons because there was no motivation to combine and because the invention is not obvious we ask that you reverse the Examiner's rejection. Thank you.

MR. KIMLIN: Thank you for coming.

Whereupon, at approximately 2:32 p.m., the proceedings were concluded.